IV.ORAL CONTRIBUTIONS

2805

Revascularization Outcomes

Monday, March 31, 2008, 10:00 a.m.-11:30 a.m.
McCormick Place, Room S106a

10:00 a.m.

2805-3 **Long-term Clinical Outcome After Implantation of Drug-eluting Compared to Bare-metal Stents in a Real World Population: Three-year Results of the BASKET Trial**

Christoph A. Kaiser, Hanspeter Brunner-La Rocca, Peter Buser, Fabian Nietlispach, Gregor Leibundgut, Franziska Bader, Matthias Pfisterer, BASKET Investigators, Department of Cardiology, University Hospital, Basel, Switzerland

Background: As compared to bare-metal stents (BMS), drug-eluting stents (DES) have been shown to reduce restenosis and target vessel revascularization (TVR) in pivotal trials with selected patients and simple lesions up to five years. The initial enthusiasm was recently tarnished by the findings of late and very late stent thrombosis after DES in real world registries and meta-analyses. The Basel Stent Kosteneffiktivitaets Trial (BASKET) was the first prospective randomized trial demonstrating an increased rate of clinical thrombosis associated events after DES compared to BMS up to 18 months (BASKET-LATE). It is unknown, whether these differences are maintained during long-term follow-up.
Methods: A total of 826 patients treated by PCI/stenting within one year (May 05, 2003 and May 31, 2004) were included and randomized to one of two DES (Cypher® , n=264 , Taxus®, n=264) or a cobalt-chromium-based BMS (Vision®, n=281). Excluded were only patients with in-stent-restenosis, vessel diameter >4mm or no consent. Patients were followed-up during 3 years for major adverse cardiac events, death, TVR, myocardial infarction and stent thrombosis. Patients were advised to stop clopidogrel after 6 months. The protocol did not allow control angiography without a clinical indication.
Results: The total population consisted of 79% men with an average age of 64+11 years presenting with stable angina in 42%, acute MI in 21% and unstable coronary syndromes in 36%. Patients had received 1.9+1.1 stents for a total stent length of 34+20mm per patient. There were no significant differences between the 3 patient groups in any of these parameters. The clinical follow-up up to 3 years will be completed by end of June 2007 and the complete results including subgroup analyses will be available at the time of the ACC annual meeting 2008.
Conclusions: The 3 year clinical effectiveness findings from BASKET will demonstrate 1) whether there is an ongoing trend for an increased rate of late thrombosis associated events after DES compared to BMS and 2) if yes, whether these events outweigh the benefits of DES regarding the reduction of restenosis.

10:15 a.m.

2805-4 **Short- and Long-term Health Related Quality of Life and Anginal Status in Patients Treated for Multivessel Coronary Artery Disease: Insights Into the ARTS-II Trial**

Ron T. van Domburg, Joost Daemen, Marie-Claude Morice, Bernard de Bruyne, Antonio Colombo, Carlos Macaya, Gert Richardt, Jaen Fajadet, Christian Hamm, Keith D. Dawkins, Pascal Franckx, Monique Schuijer, Kristel Wittebols, Magdaleen Pieters, Hans P. Stoll, Patrick W. Serruys, Erasmus Medical Center, Rotterdam, The Netherlands

Background: To determine the health related quality of life (HRQL) following sirolimus-eluting stent (SES) (CYPHER®) implantation in patients with multivessel disease and to compare outcomes with the historical results of the two arms of the Arterial Revascularization Therapies Study (ARTS-I).
Methods: ARTS-II is a 45 center, single-arm study. The HRQL outcomes were compared to the outcome of the historical cohorts of the randomized ARTS-I trial using the same inclusion and exclusion criteria. Patients were stratified by clinical site to ensure that at least 1/3 had 3-vessel disease to achieve a number of treated lesions per patient comparable to ARTS-I. HRQL was evaluated at baseline, at 1- month and at 6-, 12- and 36 months after revascularization using the Short Form Health Survey (SF-36) in patients treated with SES (n=585), BMS (n=483) or CABG (n=492).
Results: The corresponding participating rates varied from 100% at baseline to 93% at 36 months. Both stenting and CABG resulted in significant improvement of HRQL and anginal status. There was a trend towards better HRQL after CABG than BMS beyond 6 months. Already from the first month up to three years, SES patients had, on average, 10% significant better HRQL than BMS patients on all HRQL subscales (p<0.01). Up to 12 months the HRQL was better after SES than CABG and between 12 months and 36 months the HRQL of SES and CABG were identical. At all time points, angina was more prevalent in the BMS group, whereas the incidence of angina was similar in the SES and CABG groups. At three years, 10% of the SES patients had angina, 13% of the CABG patients and 20% of the BMS patients.
Conclusions: Both stenting and CABG resulted in a significant improvement in HRQL and angina. With the introduction of the drug-eluting stents, with subsequent substantial reduction of restenosis, HRQL after SES was significantly improved as compared with BMS and was similar to CABG.

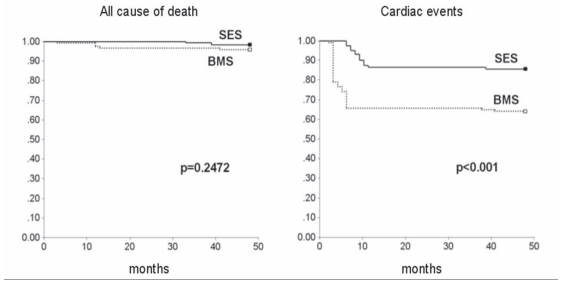
10:30 a.m.

2805-5 **Four-Year Durability of Sirolimus-Eluting Stent in Patients With Unprotected Left Main Coronary Arteries Compared With Bare-Metal Stents: Multicenter Registry in Asia**

Sunao Nakamura, Jang-Ho Bae, Yeo Hans Cahyadi, Wasan Udayachalerm, Damras Tresukosol, Sudaratana Tansuphaswadikul, New Tokyo Hospital, Chiba, Japan, Konyang University Hospital, Daejeon, South Korea

Aim: The aim of this study is to compare the safety and efficacy of Sirolimus-eluting stent (SES) and bare metal stent (BMS) on the outcome of patients with unprotected left main coronary arteries (LMT). **Methods**: Complete clinical follow-up to 4 years is being analyzed for 241 patients who received 120 SES and 121 BMS in patients with LMT (male 71.7%, mean age 70.5 yrs) in five high volume Asian centers. Lesion location of LMT was ostial 24 cases (10.0%), mid shaft 38 cases (15.8%) and distal 179 cases (74.3%). **Results**: The baseline clinical characteristics between 2 groups were similar. Angiographic and clinical success were achieved in all patients. At 4 years overall cardiac events occurred in 12.5% of SES patients and 38.0% of BMS patients (p<0.001). See figure. **Conclusion**: The use of Sirolimus-eluting stent is effective in preventing cardiac events compared with bare metal stent associated with low acute complication and these benefits is durable at least 4 years.

Four years cumulative freedom from death and cardiac events (death, myocardial infraction, CABG and PCI) in SES and BMS groups



10:45 a.m.

2805-6 **Three-year Clinical Outcome After Primary Stenting of Totally Occluded Native Coronary Arteries: PRISON II Study**

Braim M. Rahel, Maarten J. Suttorp, Gerrit J. Laarman, Jur M. ten Berg, Johannes C. Kelder, Mike A.R. Bosschaert, St Antonius Hospital, Nieuwegein, The Netherlands, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands

Background: The purpose of this study was to examine the three-year clinical outcome in patients enrolled in the Primary Stenting of Totally Occluded Native Coronary Arteries II (PRISON II) study. The PRISON II study was a prospective, randomized, single-blind, 2-center study which demonstrated that sirolimus-eluting Cypher stents (SES) significantly improved both angiographic results (at 6 months) and clinical outcome (at 6 and 12 months) compared with bare-metal BxVelocity stents (BMS).
Methods: Patients with chronic total occlusions in native coronary arteries randomized to either SES (100 patients) or BMS (100 patients) were followed clinically for three years.
Results: Between one and three years, there were infrequent additional clinical events that were equally distributed between the SES and BMS group. After three years, target lesion revascularization was 7% in the SES group versus 27% in the BMS group (p<0.001) and target vessel revascularization was seen in 11% in the SES group versus 30% in the BMS group (p=0.002). Major adverse cardiac events were noted in 10% of the SES group versus 34% in the BMS group (p<0.001). Target vessel failure was noted in 12% in the SES group versus 36% in the BMS group (p<0.001). There were no statistically significant differences in death, myocardial infarction, and stent thrombosis according to the ARC criteria between the two groups.
Conclusion: Clinical outcome up to three years after implantation of SES for total coronary occlusions continue to demonstrate a significant reduction in adverse clinical events compared with BMS without the evidence for either disproportionate late restenosis or late stent thrombosis.

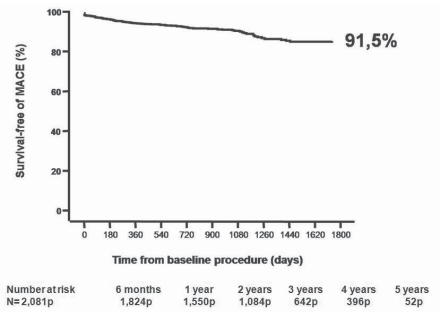
11:00 a.m.

2805-7 **Very Long-term Clinical Outcomes of the DESIRE (Drug Eluting Stents In the REal world) Registry**

Jose de Ribamar Costa, Jr., Amanda Sousa, Ricardo Costa, Adriana Moreira, Manuel Cano, Galo Maldonado, Marcos Barbosa, Maria Helena Bib, Rodolfo Staico, J Eduardo Sousa, Hospital do Coração - Associação do Sanatório Sírio, São Paulo, Brazil

Background: Drug-eluting stents (DES) have markedly reduced the need of repeat intervention in the treated lesion of selected patients. However, very long-term efficacy and safety of these new devices for the treatment of "real-world" pts is still unclear.
Methods: The DESIRE registry is a non-randomized single-center registry with consecutive pts treated solely with DES between May 2002 and May 2007. The primary end point was long-term occurrence of MACE and stent thrombosis (ST). Pts were clinically evaluated at 1, 3 and 6 months and then annually up to 5 years. ARC definition

of ST was adopted.
Results: A total of 2,081 patients (2,864 lesions and 3,120 stents) were included. The mean age was 63 years with 29% of diabetics. Mean reference vessel diameter and lesion length were 2.76±0.47mm and 16.3±8.2mm respectively. Procedural success was achieved in 98.5% of the cases. Follow-up was obtained in 96.5% of the patients. In the long-term follow-up, TLR was performed in 3.3% of the patients. Q-wave MI occurred in only 0.7% of these patients and total ST rate was 1.6% (n=33) with 17 cases (51.5%) classified as definite. The figure shows the survival-free of MACE curve up to 5 years. Cox's multivariate analysis showed treatment of acute myocardial infarction, lesion calcification, residual stenosis and stent length as independent predictors of ST.
Conclusion: The use of DES in an unselected population is associated with long-term safety and effectiveness with acceptable low rates of adverse clinical events.



11:15 a.m.

2805-8 **Risk of Death or Emergency Cardiac Surgery in Contemporary Elective Percutaneous Coronary Interventions; Implications for Percutaneous Coronary Interventions Without Onsite Bypass Surgery**

Hitinder S. Gurm, Dean E. Smith, Eva Kline-Rogers, Share David, Michael O'Donnell, Richard McNamara, Mauro Moscucci, University of Michigan Medical Center, Ann Arbor, MI

Background: There is ongoing debate on the safety of elective percutaneous coronary intervention (PCI) without onsite surgical backup. There are, however, limited data on the frequency of need for emergency coronary artery bypass surgery (CABG) in contemporary elective PCI.
Methods: We evaluated the incidence and predictors of emergency CABG and mortality among patients undergoing elective PCI in a large regional consortium.
Results: Our cohort comprised of 53,940 patients who underwent elective PCI at 19 hospitals in Michigan between1997 and 2006 A total of 143 (0.27%) patients needed emergency CABG while 97 (0.18%) died during the index hospitalization. The independent predictors of mortality were age $\geq$ 80 years (OR 5.04), age 70-79 years (OR 3.07), female gender (OR 2.01), history of dialysis dependent renal failure (OR 3.82), history of prior CABG (OR 0.32), history of chronic obstructive pulmonary disease (OR 2.22), three vessel disease (OR 2.11),and intervention on three or more lesions (OR 2.86). The independent predictors of emergency CABG were prior history of CABG (OR 0.07), prior history of PCI (OR 0.56), three vessel disease (OR 2.96) and calcified lesion (OR 2.27). In patients with no prior history of coronary revascularization, the presence of coronary artery calcification and 3 vessel disease was associated with a 2.12% incidence of emergency CABG and a 1.16% mortality rate, when compared to an emergency CABG rate of 0.28% and a mortality rate of 0.1% in patients without these adverse angiographic characteristics.
Conclusion: The incidence of emergency CABG and in-hospital mortality in elective PCI is low but not insignificant. Adverse angiographic characteristics identify patients at extremely high risk of emergency CABG and in hospital mortality. These finding might have important implications in the selection of patients for elective PCI in centers without on site cardiac surgery.